

The lack of unity determination set forth in the outstanding Official Action is believed to be improper on multiple bases, and therefore must be withdrawn.

First, the lack of unity determination violates MPEP §1893.03(d), which requires that a lack of unity determination not only list the different groups of claims, but also "...explain why each group lacks unity with each other group (i.e., why there is no single general note of concept) specifically described in the unique special technical feature in each group." The outstanding Official Action does not meet this requirement.

Instead, the Official Action seeks to justify a lack of unity requirement by noting the International Search Report has alleged that claim 1 lacks novelty in view of SROUR 5,672,346. However, it is important to note that the International Search Report finds no lack of unity of invention. In the International Preliminary Examination Report, the International Examiner examined claims 1-16 for novelty and inventive step. While it is true that the International Search Report was not established for claims 7-12, it is only because claims 7-12 were considered not to comply with the standards of industrial applicability peculiar to the PCT. However, claims 7-12 are directed to statutory subject matter under United States patent law. As such, the Examiner has had the benefit of the relevant portions of the International Search Report for claims 1-16.

Second, a determination of lack of unity is possible only when the claims of the different groups lack a "special technical feature" relative to one another. It is the burden of the Patent Office to establish the lack of any special technical features, which the outstanding Official Action plainly does not do.

In the present application, the outstanding Official Action equates the citation of one reference by the International Search Report as a lack of unity of invention. However, the Examiner's attention in this regard is directed to PCT Rule 13.2 and Part 1b of Annex B of the Administration Instructions Under the PCT, which specify that "special technical features" is defined as meaning those technical features that define a contribution with each other of the inventions, considered as a whole, makes over the prior art. In this respect, it is respectfully submitted that the outstanding Official Action fails to establish a lack of unity of invention.

Applicants note with appreciation that the outstanding Official Action also provides several suggestions to help advance prosecution in the present application. The outstanding Official Action notes that claim 16 is directed to the recitation of a use, without setting forth any steps involved in the process. Upon rejoinder of all the claims, applicants will amend claim 16 to recite preferred United States patent practice claim language.

In addition, the outstanding Official Action noted several informalities present in the claimed invention. Claims 1-15 and 17-19 of the present application have been amended to remove these informalities and to reflect preferred United States patent practice.

It is also noted that the outstanding Official Action imposed an election of species requirement. As applicants have provisionally elected Group II, it is respectfully submitted that an election of species is unnecessary at this time.

In light of the above discussion, it is believed to be apparent that the lack of unity determination set forth in the Official Action of April 17, 2002, is improper and must be withdrawn. Favorable action on the merits of all the claims 1-19 in the full scope claimed is therefore respectfully requested.

Attached hereto is a marked-up version of the changes made to the claims. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Respectfully submitted,

YOUNG & THOMPSON

By Philip A. DuBois  
Philip A. DuBois  
Agent for Applicants  
Registration No. 50,696  
745 South 23rd Street  
Arlington, VA 22202  
Telephone: 521-2297

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS:**

Claim 1 has been amended as follows:

--1. (amended) [Cell] A cell composition containing macrophages, presenting anti-infectious and hematopoietic properties.--

Claim 2 has been amended as follows:

--2. (amended) [Cell] A cell composition containing macrophages, myeloid cells and progenitor cells, with said progenitor cells being [preferably] present in a ratio of at least about [0,1%, preferably about 0,1 to 20%] 0.1%, with said myeloid cells being [preferably] present in an amount of about 10% to about 30%, with said macrophages being [preferably] in an amount of about 10 to about 60%, these percentages being expressed with respect to the total number of cells.--

Claim 3 has been amended as follows:

--3. (twice amended) [Cell] The cell composition according to claim 1, containing T lymphocytes[, preferably] in a ratio of about 10 to 60% expressed with respect to the total number of cells.--

Claim 4 has been amended as follows:

--4. (twice amended) [Cell] The cell composition according to claim 2, wherein the progenitor cells contain from about [0,1] 0.1% to about 20% of CD34<sup>+</sup> stem cells, expressed with respect to the total number of progenitor cells.--

Claim 5 has been amended as follows:

--5. (amended) [Cell] The cell composition according to claim 4, wherein the progenitor cells are generated from and [possibly] optionally included in peripheral blood mononuclear cells, and [in particular are chosen among:] are selected from the group consisting of myelo-erythroid progenitor cells, myeloid progenitor cells, lymphoid progenitor cells [or] and mixtures thereof.--

Claim 6 has been amended as follows:

--6. (twice amended) [Cell] The cell composition according to claim 2, wherein the macrophages, myeloid cells and the lymphocytes if present, are included in/or generated from blood mononuclear cells.--

Claim 7 has been amended as follows:

--7. (amended) [Process] A process for the preparation of a cell composition containing macrophages, myeloid cells and progenitor cells, with said progenitor cells being [preferably] present in an amount of about [0,1] 0.1% to about 20%, with said macrophages being [preferably] in an amount of about 10 to about 60%, these percentages being expressed with respect to the total number of cells, comprising the step of [mobilization] mobilizing the progenitor cells in the blood of a patient [for instance] by premedication of said patient with G-CSF and/or GM-CSF, or G-CSF and cyclophosphamide, thus increasing the amount of progenitor cells in peripheral blood.--

Claim 8 has been amended as follows:

--8. (amended) [Process] The process according to claim 7, further comprising [an additional step of coculture of] coculturing the blood mononuclear cells and progenitors, after washing off the platelets, the granulocytes and erythrocytes, for about 4 to about 10 days, in a medium allowing differentiation of monocytes into macrophages and myeloid progenitors into polynuclear cells.--

Claim 9 has been amended as follows:

--9. (amended) [Process] The process according to claim 8, wherein the coculture is carried out in the presence of cytokines or growth factors[,for example: IL3, IL6] selected from the group consisting of IL-3, IL-6 stem cell factor, EPO, [trhombopoitein] thrombopoitein, GM-CSF, G-CSF, [Flat-3] FLAT-3 ligand, [C-kit] C-Kit ligand [or] and their agonists.--

Claim 10 has been amended as follows:

--10. (twice amended) [Process] The process according to claim 8, further comprising [an additional step of macrophage activation] a step of activating macrophages, at the end of the coculture, [for instance] by addition of  $\gamma$ -interferon or muramyl peptides.--

Claim 11 has been amended as follows:

--11. (twice amended) [Process] The process according to claim 7, further comprising [an additional] a step of [concentration of] concentrating the cells obtained at the end of

the coculture, and resuspension in a vehicle suitable for administration to a patient.--

Claim 12 has been amended as follows:

--12. (amended) [Process] The process according to claim 11, further comprising, after the resuspension of the coculture, a step of freezing part or the totality of the resuspension.--

Claim 13 has been amended as follows:

--13. (twice amended) Cell composition [such] as obtained [according to] by the process [of] according to claim 7.--

Claim 14 has been amended as follows:

--14. (twice amended) [Pharmaceutical] The pharmaceutical composition containing, as active substance, the cell composition according to claim 1.--

Claim 15 has been amended as follows:

--15. (twice amended) Cell composition according to claim 1, [characterized by the fact that it] wherein said composition is derived from and/or included in a peripheral blood mononuclear cell composition containing:

- from about 10 to about 50% of monocytes,
- from about 10 to about 70% of lymphocytes,
- from about [0,1] 0.1 to about 20% of progenitor cells,
- from about 1 to about 50% of polynuclear cells,

- from about [0,1] 0.1 to about 20% of stem cells.--

Claim 17 has been amended as follows:

--17. (amended) [Cell] The cell composition according to claim 2, containing T lymphocytes, [preferably] in a ratio of about 10 to 60% expressed with respect to the total number of cells.--

Claim 18 has been amended as follows:

--18. (amended) [Pharmaceutical] The pharmaceutical composition containing, as active substance, the cell composition according to claim 2.--

Claim 19 has been amended as follows:

--19. (amended) [Cell] The cell composition according to claim 2, [characterized by the fact that it] wherein said composition is derived from and/or included in a peripheral blood mononuclear cell composition containing:

- from about 10 to about 50% of monocytes,
- from about 10 to about 70% of lymphocytes,
- from about [0,1] 0.1 to about 20% of progenitor cells,
- from about 1 to about 50% of polynuclear cells,
- from about [0,1] 0.1 to about 20% of stem cells.--